



Used in Lieu of PTO/SB/08A/B  
(Based on PTO 01-08 version)

Substitute for form 1449/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 11

## Complete if Known

Application Number	10/601,132
Filing Date	June 20, 2003
First Named Inventor	Anthony P. Shuber
Art Unit	1642
Examiner Name	S. E. Aeder
Attorney Docket Number	EXT-055

## U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	A1*	US-2001/039012	11-08-2001	Lapidus	
	A2*	US-2001/018180	08-30-2001	Shuber et al.	
	A3*	US-2002/001800	01-03-2002	Lapidus	
	A4*	US-2002/004201	01-10-2002	Lapidus et al.	
	A5*	US-2002/025525	02-28-2002	Shuber	
	A6*	US-2002/045183	04-18-2002	Shuber et al.	
	A7*	US-2002/048752	04-25-2002	Lapidus et al.	
	A8*	US-2002/064787	05-30-2002	Shuber et al.	
	A9*	US-2002/110810	08-15-2002	Shuber	
	A10*	US-2002/119469	08-29-2002	Shuber et al.	
	A11*	US-2002/119472	08-29-2002	Lapidus et al.	
	A12*	US-2002/123052	09-05-2002	Laken	
	A13*	US-2002/132251	09-19-2002	Shuber	
	A14*	US-2002/164631	11-07-2002	Shuber et al.	
	A15*	US-2003/044780	03-06-2003	Lapidus et al.	
	A16*	US-2003/049659	03-13-2003	Lapidus et al.	
	A17*	US-2003/087258	05-08-2003	Shuber	
	A18*	US-2004/043467	03-04-2004	Shuber et al.	
	A19*	US-2005/260638	11-24-2005	Shuber	
	A20*	US-2006/121495	06-08-2006	Shuber	
	A21*	US-2007/0202513	08-30-2007	Shuber	
	A22*	US-2007/0248546	10-25-2007	Shuber	
	A23*	US-3,413,464	11-26-1968	Hetensky	
	A24*	US-4,101,279	07-18-1978	Astam et al.	
	A25*	US-4,309,782	01-12-1982	Paulin et al.	
	A26*	US-4,333,734	06-08-1982	Fleisher	
	A27*	US-4,358,535	11-09-1982	Falkow et al.	
	A28*	US-4,445,235	05-01-1984	Slover et al.	
	A29*	US-4,535,058	08-13-1985	Weinberg et al.	
	A30*	US-4,578,358	03-25-1986	Oksman et al.	
	A31*	US-4,705,050	11-10-1987	Markham	
	A32*	US-4,735,905	04-05-1988	Parker	
	A33*	US-4,786,718	11-22-1988	Weinberg et al.	
	A34*	US-4,857,300	08-15-1989	Maksem	
	A35*	US-4,871,838	10-03-1989	Bos et al.	
	A36*	US-4,935,342	06-19-1990	Seligson et al.	
	A37*	US-4,981,783	01-01-1991	Augenlicht	
	A38*	US-4,982,615	01-08-1991	Sultan et al.	
	A39*	US-5,087,617	02-11-1992	Smith	
	A40*	US-5,126,239	06-30-1992	Livak et al.	
	A41*	US-5,137,806	08-11-1992	LeMaistre et al.	
	A42*	US-5,149,506	09-22-1992	Skiba et al.	
	A43*	US-5,196,167	03-23-1993	Guadagno et al.	

Examiner Signature	Date Considered
-----------------------	--------------------

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SA/

Substitute for form 1449/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			Application Number	10/601,132	
			Filing Date	June 20, 2003	
			First Named Inventor	Anthony P. Shuber	
			Art Unit	1642	
			Examiner Name	S. E. Aeder	
Sheet	2	of	11	Attorney Docket Number	EXT-055

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A44*	US-5,200,314	04-06-1993	Urdea	
	A45*	US-5,248,671	09-28-1993	Smith	
	A46*	US-5,272,057	12-21-1993	Smulson et al.	
	A47*	US-5,302,509	04-12-1994	Cheeseman	
	A48*	US-5,330,892	07-19-1994	Vogelstein et al.	
	A49*	US-5,331,973	07-26-1994	Fiedler et al.	
	A50*	US-5,348,855	09-20-1994	Dattagupta et al.	
	A51*	US-5,352,775	10-04-1994	Albertsen et al.	
	A52*	US-5,362,623	11-08-1994	Vogelstein et al.	
	A53*	US-5,369,004	11-29-1994	Polymeropoulos et al.	
	A54*	US-5,378,602	01-03-1995	Polymeropoulos et al.	
	A55*	US-5,380,645	01-10-1995	Vogelstein	
	A56*	US-5,380,647	01-10-1995	Bahar et al.	
	A57*	US-5,382,510	01-17-1995	Levine et al.	
	A58*	US-5,409,586	04-25-1995	Kamahori et al.	
	A59*	US-5,416,025	05-16-1995	Krepinsky et al.	
	A60*	US-5,458,761	10-17-1995	Kamahori et al.	
	A61*	US-5,463,782	11-07-1995	Carlson et al.	
	A62*	US-5,466,576	11-14-1995	Schulz et al.	
	A63*	US-5,468,610	11-21-1995	Polymeropoulos et al.	
	A64*	US-5,468,613	11-21-1995	Erllich et al.	
	A65*	US-5,482,834	01-09-1996	Gillespie	
	A66*	US-5,489,508	02-06-1996	West et al.	
	A67*	US-5,492,808	02-20-1996	de la Chapelle et al.	
	A68*	US-5,496,470	03-05-1996	Lenhart	
	A69*	US-5,506,105	04-09-1996	Haydock	
	A70*	US-5,508,164	04-16-1996	Kausch et al.	
	A71*	US-5,512,441	04-30-1996	Ronai	
	A72*	US-5,514,547	05-07-1996	Balazs et al.	
	A73*	US-5,527,676	06-18-1996	Vogelstein et al.	
	A74*	US-5,532,108	07-02-1996	Vogelstein	
	A75*	US-5,538,851	07-23-1996	Fach et al.	
	A76*	US-5,559,014	09-24-1996	Estes et al.	
	A77*	US-5,580,729	12-03-1996	Vogelstein	
	A78*	US-5,589,335	12-31-1996	Kearney et al.	
	A79*	US-5,599,662	02-04-1997	Respass	
	A80*	US-5,612,473	03-18-1997	Wu et al.	
	A81*	US-5,635,352	06-03-1997	Urdea et al.	
	A82*	US-5,641,628	06-24-1997	Bianchi	
	A83*	US-5,645,995	07-08-1997	Kieback	
	A84*	US-5,670,325	09-23-1997	Lapidus et al.	

Examiner Signature	Date Considered
-----------------------	--------------------

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SA/

Substitute for form 1449/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			Application Number	10/601,132	
			Filing Date	June 20, 2003	
			First Named Inventor	Anthony P. Shuber	
			Art Unit	1642	
			Examiner Name	S. E. Aeder	
Sheet	3	of	11	Attorney Docket Number	EXT-055

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.*	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A85*	US-5,688,643	11-18-1997	Oka et al.	
	A86*	US-5,709,998	01-20-1998	Kinzler et al.	
	A87*	US-5,710,028	01-20-1998	Eyal et al.	
	A88*	US-5,741,650	04-21-1998	Lapidus et al.	
	A89*	US-5,759,777	06-02-1998	Kearney et al.	
	A90*	US-5,830,665	11-03-1998	Shuber et al.	
	A91*	US-5,846,710	12-08-1998	Bajaj	
	A92*	US-5,856,104	01-05-1999	Chee et al.	
	A93*	US-5,882,865	03-16-1999	Vogelstein et al.	
	A94*	US-5,888,778	03-30-1999	Shuber	
	A95*	US-5,910,407	06-08-1999	Vogelstein et al.	
	A96*	US-5,916,744	06-29-1999	Taylor et al.	
	A97*	US-5,928,870	07-27-1999	Lapidus et al.	
	A98*	US-5,942,396	08-24-1999	Shiff et al.	
	A99*	US-5,952,178	09-14-1999	Lapidus et al.	
	A100*	US-5,976,800	11-02-1999	Lau et al.	
	A101*	US-6,020,137	02-01-2000	Lapidus et al.	
	A102*	US-6,037,465	03-14-2000	Hillebrand et al.	
	A103*	US-6,084,091	07-04-2000	Muller et al.	
	A104*	US-6,100,029	08-08-2000	Lapidus et al.	
	A105*	US-6,143,529	11-07-2000	Lapidus et al.	
	A106*	US-6,146,828	11-14-2000	Lapidus et al.	
	A107*	US-6,150,100	11-21-2000	Ruschoff et al.	
	A108*	US-6,156,504	12-05-2000	Gocke et al.	
	A109*	US-6,177,251	01-23-2001	Vogelstein et al.	
	A110*	US-6,214,187	04-10-2001	Hammond et al.	
	A111*	US-6,214,558	04-10-2001	Shuber et al.	
	A112*	US-6,228,596	05-08-2001	Macina et al.	
	A113*	US-6,235,474	05-22-2001	Feinberg	
	A114*	US-6,238,927	05-29-2001	Abrams et al.	
	A115*	US-6,251,660	06-26-2001	Muir et al.	
	A116*	US-6,268,136	07-31-2001	Shuber et al.	
	A117*	US-6,280,947	08-28-2001	Shuber et al.	
	A118*	US-6,300,077	10-09-2001	Shuber et al.	
	A119*	US-6,303,304	10-16-2001	Shuber et al.	
	A120*	US-6,406,857	06-18-2002	Shuber et al.	
	A121*	US-6,428,964	08-06-2002	Shuber	
	A122*	US-6,448,002	09-10-2002	Hillebrand et al.	
	A123*	US-6,498,012	12-24-2002	Laken	
	A124*	US-6,503,718	01-07-2003	Shuber et al.	
	A125*	US-6,551,777	04-22-2003	Shuber et al.	

Examiner Signature	Date Considered
--------------------	-----------------

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SA/

Substitute for form 1449/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			Application Number	10/601,132	
			Filing Date	June 20, 2003	
			First Named Inventor	Anthony P. Shuber	
			Art Unit	1642	
			Examiner Name	S. E. Aeder	
Sheet	4	of	11	Attorney Docket Number	EXT-055

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.*	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A126*	US-6,586,177	07-01-2003	Shuber	
	A127*	US-6,849,403	02-01-2005	Shuber	
	A128*	US-6,919,174	07-19-2005	Shuber	
	A129*	US-6,964,846	11-15-2005	Shuber	
	A130*	US-6,203,993 B1	03-20-2001	Shuber et al.	
	A131*	US-6,351,857 B2	03-05-2002	Slaon, III et al.	
	A132*	US-6,415,455 B1	07-09-2002	Slaon, III et al.	
	A133*	US-6,428,964 B1	08-06-2002	Shuber	
	A134*	US-6,475,738 B2	11-05-2002	Shuber et al.	
	A135*	US-6,482,595 B2	11-19-2002	Shuber et al.	

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	†*	
		Country Code*-Number*-Kind Code* (if known)					
	B1	AU-19942333	09-30-1999				
	B2	AU-A-11325/95	04-18-1996	Univ Johns Hopkins			
	B3	CA-2228769	02-27-1997	Max Planck Gesellschaft			
	B4	DE-19530132 C2	02-20-1997	Max Planck Gesellschaft		✓	
	B5	DE-19712332 A1	10-01-1998	Boehringer Mannheim GmbH		✓	
	B6	DE-19736691 A	02-25-1999	Giesing Michael Prof Dr Med		✓	
	B7	EP-0270017 A2	06-08-1988	Molecular Biosystems Inc			
	B8	EP-0284362 A2	09-28-1988	Ici Plc			
	B9	EP-0337498	10-18-1989	Montefiore Med Center			
	B10	EP-0390323 A2	10-03-1990	Univ Johns Hopkins			
	B11	EP-0391565	10-10-1990	Helena Lab Corp			
	B12	EP-0407789 B1	01-16-1991	Canon Kk			
	B13	EP-0664339 A1	07-26-1995	Wakunaga Seiyaku Kk			
	B14	GB-2327497	01-27-1999	Zeneca Ltd.			
	B15	WO-00/09751	02-24-2000	Exact Lab Inc			
	B16	WO-00/11215	03-02-2000	Exact Lab Inc			
	B17	WO-00/31298-	06-02-2000	Exact Lab Inc			
	B18	WO-00/31303	06-02-2000	Exact Lab Inc			
	B19	WO-00/31305	06-02-2000	Exact Lab Inc			
	B20	WO-00/32820	06-08-2000	Exact Lab Inc			
	B21	WO-00/50640	08-31-2000	Exact Lab Inc			
	B22	WO-00/58514	10-05-2000	Exact Lab Inc			
	B23	WO-00/60118	10-12-2000	Mosaic Technologies Inc et al.			

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SA/

Substitute for form 1449/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			Application Number	10/601,132	
			Filing Date	June 20, 2003	
			First Named Inventor	Anthony P. Shuber	
			Art Unit	1642	
			Examiner Name	S. E. Aeder	
Sheet	5	of	11	Attorney Docket Number	EXT-055

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No.	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear
	B24	WO-00/70096	11-23-2000	Exact Lab Inc	
	B25	WO-01/11083 A2	02-15-2001	Exact Lab Inc	
	B26	WO-01/18252 A2	03-15-2001	Exact Lab Inc	
	B27	WO-01/42502 A2	06-14-2001	Exact Lab Inc	
	B28	WO-01/42503 A2	06-14-2001	Exact Sciences Corp	
	B29	WO-01/42781 A2	06-14-2001	Exact Sciences Corp et al.	
	B30	WO-01/64950 A2	09-07-2001	Exact Sciences Corp	
	B31	WO-02/55740 A2	07-18-2002	Exact Sciences Corp	
	B32	WO-02/74995	09-26-2002	Exact Sciences Corp et al.	
	B33	WO/02/092858 A2	11-21-2002	Exact Sciences Corp	
	B34	WO-03/71252 A2	08-28-2003	Exact Sciences Corp	
	B35	WO-90/09455	08-23-1990	Geneco Pty Ltd	
	B36	WO-92/13103	08-06-1992	Univ Johns Hopkins et al.	
	B37	WO-92/16857	10-01-1992	Du Pont	
	B38	WO-93/18186	09-16-1993	Univ California	
	B39	WO-93/20233	10-14-1993	Univ Maryland	
	B40	WO-93/20235	10-14-1993	Univ Johns Hopkins Med	
	B41	WO-94/00603	01-06-1994	Univ Princeton et al.	
	B42	WO-94/01447	01-20-1994	Eriphyle B V et al.	
	B43	WO-94/10575	05-11-1994	Rycus Avigail et al.	
	B44	WO-94/11383	05-26-1994	Cold Spring Harbor Lab	
	B45	WO-95/00669 A	01-05-1995	Pharmacia Biotech Ab et al.	√
	B46	WO-95/07361	03-16-1995	Pasteur Institut et al.	
	B47	WO-95/09928	04-13-1995	Univ California	
	B48	WO-95/09929	04-13-1995	Univ California	
	B49	WO-95/13397	05-18-1995	Univ Johns Hopkins Med	
	B50	WO-95/15400	06-08-1995	Univ Johns Hopkins	
	B51	WO-95/16792	06-22-1995	Stroun Maurice et al.	√
	B52	WO-95/18818	07-13-1995	Philadelphia Children Hospital	
	B53	WO-95/19448	07-20-1995	Univ Johns Hopkins Med	
	B54	WO-95/25813	09-28-1995	Univ Utah Res Found et al.	
	B55	WO-96/01907	01-25-1996	Squibb Bristol Myers Co	
	B56	WO-96/06951	03-07-1996	Univ Johns Hopkins Med et al.	
	B57	WO-96/08514	03-21-1996	Tsang Kwong Y et al.	
	B58	WO-97/07239	02-27-1997	Max Planck Gesellschaft et al.	√
	B59	WO-97/09600	03-13-1997	Medical Res Council et al.	
	B60	WO-97/19191 A	05-29-1997	Oegreid Dagfinn et al.	
	B61	WO-97/23651	07-03-1997	Exact Lab Inc	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SA/

Substitute for form 1449/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				Application Number	10/601,132
				Filing Date	June 20, 2003
				First Named Inventor	Anthony P. Shuber
				Art Unit	1642
				Examiner Name	S. E. Aeder
Sheet	6	of	11	Attorney Docket Number	EXT-055

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.†	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	†6
	B62	WO-97/28450	08-07-1997	Exact Lab Inc		
	B63	WO-98/08971	03-05-1998	Invilek Gmbh et al.		✓
	B64	WO-98/38338	09-03-1998	Exact Lab Inc		
	B65	WO-98/39478	09-11-1998	Exact Lab Inc		
	B66	WO-98/58081	12-23-1998	Exact Lab Inc		
	B67	WO-98/58084	12-23-1998	Exact Lab Inc		
	B68	WO-99/07894	02-18-1999	Wisconsin Alumni Res Found et al.		
	B69	WO-99/07895	02-18-1999	Ludwig Inst Cancer Res et al.		
	B70	WO-99/10528	03-04-1999	Giesing Michael et al.		✓
	B71	WO-99/20798	04-29-1999	Exact Lab Inc		
	B72	WO-99/26724	06-03-1999	Mosaic Technologies et al.		
	B73	WO-99/28507	06-10-1999	Exact Lab Inc		
	B74	WO-99/53316	10-21-1999	Exact Lab Inc		
	B75	WO-99/55912	11-04-1999	Exact Lab Inc		
	B76	WO-99/66077	12-23-1999	Exact Lab Inc		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

†Applicant's unique citation designation number (optional).

‡Applicant is to place a check mark here if English language Translation is attached.

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with a single asterisk (\*) not to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. † Applicant's unique citation designation number (optional). ‡ See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. § Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ¶ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \* Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. \* Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				†2
	C1	Alquist et al. "Universal Deletion of Aerodigestive Cancers by Assay of Nanoprotic Human DNA in Stool," Presented at Digestive Diseases Week Annual Conference, San Diego, CA, May 2000.				
	C2	Aaltonen et al. (1994) "Replication Errors in Benign and Malignant Tumors from Hereditary Nonpolyposis Colorectal Cancer Patients" Cancer Research 54: 1645-1648.				
	C3	Aaltonen et al. (1998) "Incidence of Hereditary Nonpolyposis Colorectal Cancer and the Feasibility of Molecular Screening for the Disease" The New England Journal of Medicine 338: 1481-1487.				

Examiner Signature	Date Considered
--------------------	-----------------

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SA/

Substitute for form 1449/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			Application Number	10/601,132	
			Filing Date	June 20, 2003	
			First Named Inventor	Anthony P. Shuber	
			Art Unit	1642	
			Examiner Name	S. E. Aeder	
Sheet	7	of	11	Attorney Docket Number	EXT-055

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No.	include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
	C4	Allen et al. (1997) "Morphological and biochemical characterization and analysis of apoptotis." J Pharm. & Toxicol. Methods, Vol. 37, No. 4, pp. 215-28.			
	C5	Ambrosini et al. "A novel anti-apoptosis gene, surviving, expressed in cancer and lymphoma" Nature Medicine, Vol. 3, No. 8, pp. 917-921, August 1997.			
	C6	Anker et al. (1999) "Detection of Circulating Tumour DNA in the Blood (plasma/serum) of Cancer Patients," Cancer and Metastasis Reviews, Vol. 18, pp.65-73.			
	C7	Arber et al. (1997) "A K-ras Oncogene Increases Resistance to Sulindac-Induced Apoptosis in Rat Enterocytes," Gastroenterology, Vol. 113, No. 6, pp. 1892-1900.			
	C8	Bernstein et al. "A Bile Acid-induced Apoptosis Assay for Colon-Cancer Risk and Associated Quality Control Studies," Cancer Research, Vol. 59, pp. 2353-2357, 1999.			
	C9	Bertario et al. (1999) "Risk of Colorectal Cancer Following Colonoscopic Polypectomy," Tumori 85: 157-162.			
	C10	Blum (1995) "Colorectal Cancer: Future Population Screening for Early Colorectal Cancer," European Journal of Cancer, Vol. 31A, pp. 1369-1372.			
	C11	Bohm et al. (1977) "Deletion Analysis at the DEL-27, APC and MTS1 Loci in Bladder Cancer: LOH at the DEL-27 Locus on 5p13-12 is a Prognostic Marker of Tumor Progression," Int. J. Cancer (Pred. Oncol.), 74:291-295.			
	C12	Bos et al. (May 28, 1987) "Prevalence of ras Gene Mutations in Human Colorectal Cancers," Nature, Vol. 327, pp. 293-297.			
	C13	Caldas et al. (1994) "Detection of K-ras Mutations in the Stool of Patients with Pancreatic Adenocarcinoma and Pancreatic Ductal Hyperplasia," Cancer Research, Vol. 54, pp. 3568-3573.			
	C14	Capozzi et al. (1999) "Evaluation of the Replication Error Phenotype in Relation to Molecular and Clinicopathological Features in Hereditary and Early Onset Colorectal Cancer," European Journal of Cancer 35: 289-295.			
	C15	Cave et al. (1994) "Reliability of PCR Directly from Stool Samples: Usefulness of an Internal Standard," BioTechniques, Vol. 16, No. 5, pp. 809-810.			
	C16	Cawkwell et al. (1994) "Frequency of allele loss of DCC, p53, Rb1, Wt1, NF1, NM23 and APC/MCC in colorectal cancer assayed by fluorescent multiplex polymerase chain reaction," B. J. Can., Vol. 70, pp. 813-818.			
	C17	Chapelle (1999) "Testing Tumors for Microsatellite Instability," European Journal of Human Genetics 7: 407-408.			
	C18	Charlesworth et al. (1994) "The Evolutionary Dynamics of Repetitive DNA in Eukaryotes," Nature, Vol. 371, pp. 215-220.			
	C19	Chen et al. (1997) "Microsatellite Instability in Sporadic-Colon-Cancer Patients With and Without Liver Metastases" International Journal of Cancer 74: 470-474.			
	C20	Chen et al. (1996), "Detection of Single-Base Mutations by a Competitive Mobility Shift Assay," Analytical Biochemistry, CIS, Academic, Press, Vol. 239, No. 1, pp. 61-69.			
	C21	Coll et al. (1989) "Evaluation of a Rapid Method of Extracting DNA from Stool Samples for Use in Hybridization Assays," Journal of Clinical Microbiology, Vol. 27, No. 10, pp. 2245-2248.			
	C22	Coombs et al. (1996) "A Rapid, Simple, and User-Friendly Method for DNA Extraction from Clinical Stool Samples," ASM 1996 General Meeting, New Orleans, LA.			

Examiner Signature	Date Considered
--------------------	-----------------

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SA/

Substitute for form 1449/PTO			<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			Application Number	10/601,132
			Filing Date	June 20, 2003
			First Named Inventor	Anthony P. Shuber
			Art Unit	1642
			Examiner Name	S. E. Aeder
			Attorney Docket Number	EXT-055
Sheet	8	of	11	

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	C23	Coughlin et al. (1999) "Public Health Perspectives on Testing for Colorectal Cancer Susceptibility Genes" American Journal of Preventive Medicine 16: 99-104.		
	C24	Croitoru et al. "Reduce, Reuse, and Recycle: Shedding Light on Shedding Cells," Gastroenterology, Vol. 105, pp. 1243-1246, October 1993.		
	C25	Cunningham C. and M.G. Dunlop, (1996) "Molecular Genetic Basis of Colorectal Cancer Susceptibility," British Journal of Surgery, Vol. 83, pp. 321-329.		
	C26	Deng et al. (1996) "Loss of Heterozygosity in Normal Tissue Adjacent to Breast Carcinomas," Science, Vol. 274, pp. 2057-2059.		
	C27	Dennin (1979) "DNA of Free and Complexed Origin in Human Plasma: Concentration and Length Distribution," Klin. Wochenschr. Vol. 57, pp. 451-456.		
	C28	Depraetere "Eat me- Signals of apoptotic bodies," Nature Cell Biology, Vol. 2, pg. E 104, June 2000.		
	C29	Deuter et al. (1995) "A Method for Preparation of Fecal DNA Suitable for PCR," Nucleic Acids Research, Vol. 23, No. 18, pp. 3800-3801.		
	C30	Dib et al. (1996) "A Comprehensive Genetic Map of the Human Genome Based on 5,264 Microsatellites," Nature Vol. 380, pp. 152-154.		
	C31	Duffy (1995) "Can Molecular Markers Now be Used for Early Diagnosis of Malignancy?" Clin. Chem, Vol. 41, No. 10, pp. 1410-1413.		
	C32	Eads et al. (1999) "CpG island hypermethylation in human colorectal tumors is not associated with DNA methyltransferase overexpression." Cancer Research, Vol. 59, No. 10, pp. 2301-2306.		
	C33	Eguchi et al. (1996) "Mutations of the p53 Gene in the Stool of Patients with Resectable Colorectal Cancer," Cancer Supplement, Vol. 77, No. 8, pp. 1707-1710.		
	C34	Emlen et al. (1984) "Effect of DNA Size and Strandedness on the <i>in vivo</i> Clearance and Organ Localization of DNA," Clin. Exp. Immunol., Vol. 56, pp. 185-192.		
	C35	Fearon (1995) "Molecular Abnormalities in Colon and Rectal Cancer," The Molecular Basis of Cancer, pp. 340-357.		
	C36	Finkel (1999) "Does Cancer Therapy Trigger Cell Suicide?," Science, Vol. 286, pp.2256-2258.		
	C37	Garewal et al. (1996) "Reduced Bile Acid-induced Apoptosis in "Normal," Colorectal Mucosa: A Potential Biological Marker for Cancer Risk" Cancer Research, Vol. 56, pp. 1480-1483.		
	C38	Giacona et al. (1998) "Cell-Free DNA in Human Blood Plasma: Length Measurements in Patients with Pancreatic Cancer and Healthy Controls," Pancreas, Vol. 17, No. 1, pp. 89-97.		
	C39	Grossman et al. (1988), "Colonoscopic Screening of persons With Suspected Risk Factors for Colon Cancer," Gastroenterology 94: 395-400.		
	C40	Gyllenstein et al. (1995) "Sequencing of In Vitro Amplified DNA," Recombinant DNA Methodology II, (Wu, ed.), pp. 565-578.		
	C41	Hall et al. "Regulation of cell number in the mammalian gastrointestinal tract: the importance of apoptosis," Journal of Cell Science, Vol. 107, pp. 3569-3577, 1994.		
	C42	Hasegawa et al. (1995) "Detection of K-ras Mutations in DNAs Isolated From Feces of Patients with Colorectal Tumors by Mutant-Allele-Specific Amplification (MASA)," Oncogene, Vol. 10, pp. 1441-1445.		

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SA/



Substitute for form 1449/PTO			<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>			Application Number	10/601,132
			Filing Date	June 20, 2003
			First Named Inventor	Anthony P. Shuber
			Art Unit	1642
			Examiner Name	S. E. Aeder
			Attorney Docket Number	EXT-055
Sheet	9	of	11	

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	C43	Hettis "To Die or Not to Die, An Overview of Apoptosis and Its Role in Disease," JAMA, Vol. 279, No. 4, pp. 300-307, January 28, 1998.		
	C44	Hibi et al. (1998) "Molecular Detection of Genetic Alterations in the Serum of Colorectal Cancer Patients," Cancer Research, Vol. 58, pp. 1405-1407.		
	C45	Hickman et al. (1994), "Apoptosis and cancer chemotherapy," Phil. Trans. R. Soc. Lond., 345:319-325.		
	C46	Hoang et al. (1997) "BAT-26, an Indicator of the Replication Error Phenotype in Colorectal Cancers and Cell Lines" Cancer Research 57: 300-303.		
	C47	Honchel et al. (1995) "Genomic Instability in Neoplasia," Seminars in Cell Biology, Vol. 6, pp. 45-52.		
	C48	Iino et al. (1999) "DNA Microsatellite Instability in Hyperplastic Polyps, Serrated Adenomas, and Mixed Polyps: a Mild Mutator Pathway for Colorectal Cancer?" Journal of Clinical Pathology 52: 5-9.		
	C49	Iniesta et al. (1998) "Genetic Abnormalities and Microsatellite Instability in Colorectal Cancer," Cancer Detection and Prevention 22: 383-395.		
	C50	Ishimaru et al. (1995) "Microsatellite Instability in Primary and Metastatic Colorectal Cancers," International Journal of Cancer 64: 153-157.		
	C51	Jarvinen et al. (1995) "Screening Reduces Colorectal Cancer Rate in Families With Hereditary Nonpolyposis Colorectal Cancer," Gastroenterology 108: 1405-1411.		
	C52	Jernvall et al. (1999) "Microsatellite Instability: Impact on Cancer Progression in Proximal and Distal Colorectal Cancers," European Journal of Cancer 35: 197-201.		
	C53	Jessup et al. (1992) "The Biology of Colorectal Carcinoma," Current Problems in Cancer pp. 263-328.		
	C54	Kawakami et al. (2000) "Hypermethylated APC DNA in Plasma and Prognosis of Patients with Colorectal Carcinoma," Int. J. Cancer (Pred. Oncol.) 84:404-409.		
	C55	Kawasaki et al. (1998) "Inhibition of Apoptosis by Surviving Predicts Shorter Survival Rates in Colorectal Cancer," Cancer Research, Vol. 58, pp. 5071-5074.		
	C56	Kim et al. (1998) "Microsatellite Instability in Young Patients With Colorectal Cancer," Pathology International 48: 586-594.		
	C57	Ko et al. (1999) "Genomic Instability and Alterations in Apc, Mcc and Dcc in Hong Kong Patients with Colorectal Carcinoma," Int. J. Cancer (Pred. Oncol.), 84:404-409.		
	C58	Konishi et al. (1996) "Molecular Nature of Colon Tumors in Hereditary Nonpolyposis Colon Cancer, Familial Polyposis, and Sporadic Colon Cancer," Gastroenterology 111: 307-317.		
	C59	Lamberti et al. (1999) "Microsatellite Instability - a Useful Diagnostic Tool to Select Patients at High Risk for Hereditary Non-Polyposis Colorectal Cancer: A Study in Different Groups of Patients With Colorectal Cancer," Gut 44: 839-843.		
	C60	Lengauer et al. (1998) "Genetic Instabilities in Human Cancers," Nature, Vol. 396, pp. 643-649.		
	C61	Leon et al. (1977) "Free DNA in the Serum of Cancer Patients and the Effect of Therapy," Cancer Research, Vol. 37, pp. 646-650.		

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SA/

Substitute for form 1449/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			Application Number	10/601,132	
			Filing Date	June 20, 2003	
			First Named Inventor	Anthony P. Shuber	
			Art Unit	1642	
			Examiner Name	S. E. Aeder	
Sheet	10	of	11	Attorney Docket Number	EXT-055

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	C62	Lipkin "Biomarkers of Increased Susceptibility to Gastrointestinal Cancer: New Application to Studies of Cancer Prevention in Human Subjects," Cancer Research, Vol. 48, pp. 235-245, January 15, 1998.		
	C63	Leonart et al. (1998) "Microsatellite Instability and p53 Mutations in Sporadic Right and Left Colon Carcinoma" American Cancer Society 83: 889-895.		
	C64	Loktionov et al. (1995) "Early Detection of Cancer-Associated Gene Alterations in DNA Isolated from Rat Feces During Intestinal Tumor Induction with 1,2-Dimethylhydrazine," International Journal of Oncology, Vol. 6, pp. 437-445.		
	C65	Mulcahy et al. (February 1998) "A Prospective Study of K-ras Mutations in the Plasma of Pancreatic Cancer Patients," Clinical Cancer Research Vol. 4, pp. 271-275.		
	C66	Nollau et al. (1996) "Detection of K-ras Mutations in Stools of Patients with Colorectal Cancer by Mutant-Enriched PCR," Int. J. Cancer, Vol. 66 pp. 332-336.		
	C67	Nollau et al. (May 1996) "Isolation of DNA from Stool and Bodily Fluids for PCR Amplification," BioTechniques, Vol. 20, No. 5, pp. 784-788.		
	C68	Park et al. (1999) "Gene-Environment Interaction in Hereditary Nonpolyposis Colorectal Cancer with Implications for Diagnosis and Genetic Testing," International Journal of Cancer 82: 516-519.		
	C69	Payne et al. "Role of Apoptosis in Biology and Pathology: Resistance to Apoptosis in Colon Carcinomas & Ultrastructural Pathology," Vol. 19, pp. 221-248, 1995.		
	C70	Ponz de Leon et al. (1998) "Frequency and Type of Colorectal Tumors in Asymptomatic High-Risk Individuals in Families with Hereditary Nonpolyposis Colorectal Cancer," Cancer Epidemiology, Biomarkers & Prevention 7: 639-641.		
	C71	Ponz de Leon et al. (1999) "Hereditary Colorectal Cancer in the General Population: From Cancer Registration to Molecular Diagnosis," Gut 45: 32-38.		
	C72	Pyatt et al. (1999) "Polymorphic Variation at the BAT-25 and BAT-26 Loci in Individuals of African Origin," American Journal of Pathology 155: 349-353.		
	C73	Rashid et al. (1999) "Genetic Epidemiology of Mutated K-ras Proto-Oncogene, Altered Suppressor Genes, and Microsatellite Instability in Colorectal Adenomas," Gut 44: 826-833.		
	C74	Ravelingien et al. (1995) "Contribution of Molecular Oncology in the Detection of Colorectal Carcinomas," Acta Gastro-Enterologica Belgica, Vol. 58, pp. 270-273.		
	C75	Ridanpaa et al. (1995) "Detection of Loss of Heterozygosity in the p53 Tumor Suppressor Gene Using a PCR-based Assay," Path. Res. Pract., Vol. 191, pp. 399-402.		
	C76	Salahshor et al. (1999) "Microsatellite Instability in Sporadic Colorectal Cancer is Not an Independent Prognostic Factor" British Journal of Cancer 81: 190-193.		
	C77	Samowitz et al. (1995) "Microsatellite Instability in Human Colonic Cancer Is Not a Useful Clinical Indicator of Familial Colorectal Cancer," Gastroenterology 109: 1765-1771.		
	C78	Samowitz et al. (1997) "Microsatellite Instability in Colorectal Adenomas," Gastroenterology 112: 1515-1519.		
	C79	Samowitz et al. (1999) "BAT-26 and BAT-40 Instability in Colorectal Adenomas and Carcinomas and Germline Polymorphisms," American Journal of Pathology 154: 1637-1641.		

Examiner Signature	Date Considered
-----------------------	--------------------

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SA/

Substitute for form 1449/PTO			<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>			Application Number	10/601,132
			Filing Date	June 20, 2003
			First Named Inventor	Anthony P. Shuber
			Art Unit	1642
			Examiner Name	S. E. Aeder
			Attorney Docket Number	EXT-055
Sheet	11	of	11	

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	C80	Shapiro et al. (June 1983) "Determination of Circulating DNA Levels in Patients with Benign or Malignant Gastrointestinal Disease," Cancer, Vol. 51, No. 11, pp. 2116-2120.		
	C81	Sidransky (1997) "Nucleic acid-based methods for the detection of cancer," Science, Vol. 278, No. 5340, pp. 1054-1057.		
	C82	Sidransky et al. (1992) "Identification of ras Oncogene Mutations in the Stool of Patients with Curable Colorectal Tumors," Science, Vol. 256, pp. 102-105.		
	C83	Skoletsky et al. (1998) "High frequency of detecting amplifiable DNA in stools of apparently normal individuals," Gastroenterology, Vol. 114, No. 4, p A681.		
	C84	Smith-Ravin et al. (1995) "Detection of c-Ki-ras Mutations in Fecal Samples from Sporadic Colorectal Cancer Patients," Gut, Vol. 36, pp. 81-86.		
	C85	Syngal et al. (1998) "Benefits of Colonoscopic Surveillance and Prophylactic Colectomy in Patients With Hereditary Nonpolyposis Colorectal Cancer Mutations," Annals of Internal Medicine 129: 787-796.		
	C86	Syngal et al. (1999) "Interpretation of Genetic Test Results for Hereditary Nonpolyposis Colorectal Cancer," JAMA 282: 247.		
	C87	Takeda et al. (1993) "Detection of K-ras Mutation in Sputum by Mutant-Allele-Specific Amplification (MASA)," Human Mutation, Vol. 2, pp. 112-117.		
	C88	Thibodeau et al. (1993) "Microsatellite Instability in Cancer of the Proximal Colon," Science, Vol. 260, pp. 816-819.		
	C89	Tsujitani et al. (1996) "Apoptotic Cell Death and Its Relationship to Carcinogenesis in Colorectal Carcinoma," Cancer Supplement, Vol. 77, No. 8, pp. 1711-1716.		
	C90	Vogelstein, et al. (1999) "Digital PCR," Proc. Natl. Acad. Sci. USA, Vol. 96, pp. 3543-3557.		
	C91	Zhou et al. (1997) "Allelic Profiles of Mononucleotide Repeat Microsatellites in Control Individuals and in Colorectal Tumors With and Without Replication Errors," Oncogene 15: 1713-1718.		
	C92	Zhou et al. (1998) "Determination of the Replication Error Phenotype in Human Tumors Without the Requirement for Matching Normal DNA by Analysis of Mononucleotide Repeat Microsatellites," Genes. Chromosomes & Cancer 21: 101-107.		

LIBC/3251029.1

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SA/



Used in Lieu of PTO/SB/08A/B  
(Based on PTO 01-08 version)

Substitute for form 1449/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	10/601,132
		Filing Date	June 20, 2003
		First Named Inventor	Anthony P. Shuber
		Art Unit	1642
		Examiner Name	S. E. Aeder
Sheet	1	of	11
		Attorney Docket Number	EXT-055

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	A1*	US-2001/039012	11-08-2001	Lapidus	
	A2*	US-2001/018180	08-30-2001	Shuber et al.	
	A3*	US-2002/001800	01-03-2002	Lapidus	
	A4*	US-2002/004201	01-10-2002	Lapidus et al.	
	A5*	US-2002/025525	02-28-2002	Shuber	
	A6*	US-2002/045183	04-18-2002	Shuber et al.	
	A7*	US-2002/048752	04-25-2002	Lapidus et al.	
	A8*	US-2002/064787	05-30-2002	Shuber et al.	
	A9*	US-2002/110810	08-15-2002	Shuber	
	A10*	US-2002/119469	08-29-2002	Shuber et al.	
	A11*	US-2002/119472	08-29-2002	Lapidus et al.	
	A12*	US-2002/123052	09-05-2002	Laken	
	A13*	US-2002/132251	09-19-2002	Shuber	
	A14*	US-2002/164631	11-07-2002	Shuber et al.	
	A15*	US-2003/044780	03-06-2003	Lapidus et al.	
	A16*	US-2003/049659	03-13-2003	Lapidus et al.	
	A17*	US-2003/087258	05-08-2003	Shuber	
	A18*	US-2004/043467	03-04-2004	Shuber et al.	
	A19*	US-2005/260638	11-24-2005	Shuber	
	A20*	US-2006/121495	06-08-2006	Shuber	
	A21*	US-2007/0202513	08-30-2007	Shuber	
	A22*	US-2007/0248546	10-25-2007	Shuber	
	A23*	US-3,413,464	11-26-1968	Helensky	
	A24*	US-4,101,279	07-18-1978	Aslam et al.	
	A25*	US-4,309,782	01-12-1982	Paulin et al.	
	A26*	US-4,333,734	06-08-1982	Fleisher	
	A27*	US-4,358,535	11-09-1982	Falkow et al.	
	A28*	US-4,445,235	05-01-1984	Slover et al.	
	A29*	US-4,535,058	08-13-1985	Weinberg et al.	
	A30*	US-4,578,358	03-25-1986	Oksman et al.	
	A31*	US-4,705,050	11-10-1987	Markham	
	A32*	US-4,735,905	04-05-1988	Parker	
	A33*	US-4,786,718	11-22-1988	Weinberg et al.	
	A34*	US-4,857,300	08-15-1989	Maksem	
	A35*	US-4,871,838	10-03-1989	Bos et al.	
	A36*	US-4,935,342	06-19-1990	Seligson et al.	
	A37*	US-4,981,783	01-01-1991	Augenlicht	
	A38*	US-4,982,615	01-08-1991	Sultan et al.	
	A39*	US-5,087,617	02-11-1992	Smith	
	A40*	US-5,126,239	06-30-1992	Livak et al.	
	A41*	US-5,137,806	08-11-1992	LeMaistre et al	
	A42*	US-5,149,506	09-22-1992	Skiba et al.	
	A43*	US-5,196,167	03-23-1993	Guadagno et al.	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SA/

Substitute for form 1449/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			Application Number	10/601,132	
			Filing Date	June 20, 2003	
			First Named Inventor	Anthony P. Shuber	
			Art Unit	1642	
			Examiner Name	S. E. Aeder	
Sheet	2	of	11	Attorney Docket Number	EXT-055

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.*	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A44*	US-5,200,314	04-06-1993	Urdea	
	A45*	US-5,248,671	09-28-1993	Smith	
	A46*	US-5,272,057	12-21-1993	Smulson et al.	
	A47*	US-5,302,509	04-12-1994	Cheeseman	
	A48*	US-5,330,892	07-19-1994	Vogelstein et al.	
	A49*	US-5,331,973	07-26-1994	Fiedler et al.	
	A50*	US-5,348,855	09-20-1994	Dattagupta et al.	
	A51*	US-5,352,775	10-04-1994	Albertsen et al.	
	A52*	US-5,362,623	11-08-1994	Vogelstein et al.	
	A53*	US-5,369,004	11-29-1994	Polymeropoulos et al.	
	A54*	US-5,378,602	01-03-1995	Polymeropoulos et al.	
	A55*	US-5,380,645	01-10-1995	Vogelstein	
	A56*	US-5,380,647	01-10-1995	Bahar et al.	
	A57*	US-5,382,510	01-17-1995	Levine et al.	
	A58*	US-5,409,586	04-25-1995	Kamahori et al.	
	A59*	US-5,416,025	05-16-1995	Krepinsky et al.	
	A60*	US-5,458,761	10-17-1995	Kamahori et al.	
	A61*	US-5,463,782	11-07-1995	Carlson et al.	
	A62*	US-5,466,576	11-14-1995	Schulz et al.	
	A63*	US-5,468,610	11-21-1995	Polymeropoulos et al.	
	A64*	US-5,468,613	11-21-1995	Erlich et al.	
	A65*	US-5,482,834	01-09-1996	Gillespie	
	A66*	US-5,489,508	02-06-1996	West et al.	
	A67*	US-5,492,808	02-20-1996	de la Chapelle et al.	
	A68*	US-5,496,470	03-05-1996	Lenhart	
	A69*	US-5,506,105	04-09-1996	Haydock	
	A70*	US-5,508,164	04-16-1996	Kausch et al.	
	A71*	US-5,512,441	04-30-1996	Ronai	
	A72*	US-5,514,547	05-07-1996	Balazs et al.	
	A73*	US-5,527,676	06-18-1996	Vogelstein et al.	
	A74*	US-5,532,108	07-02-1996	Vogelstein	
	A75*	US-5,538,851	07-23-1996	Fach et al.	
	A76*	US-5,559,014	09-24-1996	Estes et al.	
	A77*	US-5,580,729	12-03-1996	Vogelstein	
	A78*	US-5,589,335	12-31-1996	Kearney et al.	
	A79*	US-5,599,662	02-04-1997	Respass	
	A80*	US-5,612,473	03-18-1997	Wu et al.	
	A81*	US-5,635,352	06-03-1997	Urdea et al.	
	A82*	US-5,641,628	06-24-1997	Bianchi	
	A83*	US-5,645,995	07-08-1997	Kieback	
	A84*	US-5,670,325	09-23-1997	Lapidus et al.	

Examiner Signature	Date Considered
--------------------	-----------------

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SA/

Substitute for form 1449/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			Application Number	10/601,132	
			Filing Date	June 20, 2003	
			First Named Inventor	Anthony P. Shuber	
			Art Unit	1642	
			Examiner Name	S. E. Aeder	
Sheet	3	of	11	Attorney Docket Number	EXT-055

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A85*	US-5,688,643	11-18-1997	Oka et al.	
	A86*	US-5,709,998	01-20-1998	Kinzler et al.	
	A87*	US-5,710,028	01-20-1998	Eyal et al.	
	A88*	US-5,741,650	04-21-1998	Lapidus et al.	
	A89*	US-5,759,777	06-02-1998	Kearney et al.	
	A90*	US-5,830,665	11-03-1998	Shuber et al.	
	A91*	US-5,846,710	12-08-1998	Bajaj	
	A92*	US-5,856,104	01-05-1999	Chee et al.	
	A93*	US-5,882,865	03-16-1999	Vogelstein et al.	
	A94*	US-5,888,778	03-30-1999	Shuber	
	A95*	US-5,910,407	06-08-1999	Vogelstein et al.	
	A96*	US-5,916,744	06-29-1999	Taylor et al.	
	A97*	US-5,928,870	07-27-1999	Lapidus et al.	
	A98*	US-5,942,396	08-24-1999	Shiff et al.	
	A99*	US-5,952,178	09-14-1999	Lapidus et al.	
	A100*	US-5,976,800	11-02-1999	Lau et al.	
	A101*	US-6,020,137	02-01-2000	Lapidus et al.	
	A102*	US-6,037,465	03-14-2000	Hillebrand et al.	
	A103*	US-6,084,091	07-04-2000	Muller et al.	
	A104*	US-6,100,029	08-08-2000	Lapidus et al.	
	A105*	US-6,143,529	11-07-2000	Lapidus et al.	
	A106*	US-6,146,828	11-14-2000	Lapidus et al.	
	A107*	US-6,150,100	11-21-2000	Ruschoff et al.	
	A108*	US-6,156,504	12-05-2000	Gocke et al.	
	A109*	US-6,177,251	01-23-2001	Vogelstein et al.	
	A110*	US-6,214,187	04-10-2001	Hammond et al.	
	A111*	US-6,214,558	04-10-2001	Shuber et al.	
	A112*	US-6,228,596	05-08-2001	Macina et al.	
	A113*	US-6,235,474	05-22-2001	Feinberg	
	A114*	US-6,238,927	05-29-2001	Abrams et al.	
	A115*	US-6,251,660	06-26-2001	Muir et al.	
	A116*	US-6,268,136	07-31-2001	Shuber et al.	
	A117*	US-6,280,947	08-28-2001	Shuber et al.	
	A118*	US-6,300,077	10-09-2001	Shuber et al.	
	A119*	US-6,303,304	10-16-2001	Shuber et al.	
	A120*	US-6,406,857	06-18-2002	Shuber et al.	
	A121*	US-6,428,964	08-06-2002	Shuber	
	A122*	US-6,448,002	09-10-2002	Hillebrand et al.	
	A123*	US-6,498,012	12-24-2002	Laken	
	A124*	US-6,503,718	01-07-2003	Shuber et al.	
	A125*	US-6,551,777	04-22-2003	Shuber et al.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SA/

Substitute for form 1449/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				Application Number	10/601,132
				Filing Date	June 20, 2003
				First Named Inventor	Anthony P. Shuber
				Art Unit	1642
				Examiner Name	S. E. Aeder
Sheet	4	of	11	Attorney Docket Number	EXT-055

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.*	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A126*	US-6,586,177	07-01-2003	Shuber	
	A127*	US-6,849,403	02-01-2005	Shuber	
	A128*	US-6,919,174	07-19-2005	Shuber	
	A129*	US-6,964,846	11-15-2005	Shuber	
	A130*	US-6,203,993 B1	03-20-2001	Shuber et al.	
	A131*	US-6,351,857 B2	03-05-2002	Slaon, III et al.	
	A132*	US-6,415,455 B1	07-09-2002	Slaon, III et al.	
	A133*	US-6,428,964 B1	08-06-2002	Shuber	
	A134*	US-6,475,738 B2	11-05-2002	Shuber et al.	
	A135*	US-6,482,595 B2	11-19-2002	Shuber et al.	

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.*	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear		†*
		Country Code*-Number*-Kind Code* (if known)					
	B1	AU-19942333	09-30-1999				
	B2	AU-A-11325/95	04-18-1996	Univ Johns Hopkins			
	B3	CA-2228769	02-27-1997	Max Planck Gesellschaft			
	B4	DE-19530132 C2	02-20-1997	Max Planck Gesellschaft			✓
	B5	DE-19712332 A1	10-01-1998	Boehringer Mannheim GmbH			✓
	B6	DE-19736691 A	02-25-1999	Giesing Michael Prof Dr Med			✓
	B7	EP-0270017 A2	06-08-1988	Molecular Biosystems Inc			
	B8	EP-0284362 A2	09-28-1988	Ici Plc			
	B9	EP-0337498	10-18-1989	Montefiore Med Center			
	B10	EP-0390323 A2	10-03-1990	Univ Johns Hopkins			
	B11	EP-0391565	10-10-1990	Helena Lab Corp			
	B12	EP-0407789 B1	01-16-1991	Canon Kk			
	B13	EP-0664339 A1	07-26-1995	Wakunaga Seiyaku Kk			
	B14	GB-2327497	01-27-1999	Zeneca Ltd.			
	B15	WO-00/09751	02-24-2000	Exact Lab Inc			
	B16	WO-00/11215	03-02-2000	Exact Lab Inc			
	B17	WO-00/31298-	06-02-2000	Exact Lab Inc			
	B18	WO-00/31303	06-02-2000	Exact Lab Inc			
	B19	WO-00/31305	06-02-2000	Exact Lab Inc			
	B20	WO-00/32820	06-08-2000	Exact Lab Inc			
	B21	WO-00/50640	08-31-2000	Exact Lab Inc			
	B22	WO-00/58514	10-05-2000	Exact Lab Inc			
	B23	WO-00/60118	10-12-2000	Mosaic Technologies Inc et al.			

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SA/

Substitute for form 1449/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			Application Number	10/601,132	
			Filing Date	June 20, 2003	
			First Named Inventor	Anthony P. Shuber	
			Art Unit	1642	
			Examiner Name	S. E. Aeder	
Sheet	5	of	11	Attorney Docket Number	EXT-055

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>4</sup>
	B24	WO-00/70096	11-23-2000	Exact Lab Inc		
	B25	WO-01/11083 A2	02-15-2001	Exact Lab Inc		
	B26	WO-01/18252 A2	03-15-2001	Exact Lab Inc		
	B27	WO-01/42502 A2	06-14-2001	Exact Lab Inc		
	B28	WO-01/42503 A2	06-14-2001	Exact Sciences Corp		
	B29	WO-01/42781 A2	06-14-2001	Exact Sciences Corp et al.		
	B30	WO-01/64950 A2	09-07-2001	Exact Sciences Corp		
	B31	WO-02/55740 A2	07-18-2002	Exact Sciences Corp		
	B32	WO-02/74995	09-26-2002	Exact Sciences Corp et al.		
	B33	WO/02/092858 A2	11-21-2002	Exact Sciences Corp		
	B34	WO-03/71252 A2	08-28-2003	Exact Sciences Corp		
	B35	WO-90/09455	08-23-1990	Geneco Pty Ltd		
	B36	WO-92/13103	08-06-1992	Univ Johns Hopkins et al.		
	B37	WO-92/16657	10-01-1992	Du Pont		
	B38	WO-93/18186	09-16-1993	Univ California		
	B39	WO-93/20233	10-14-1993	Univ Maryland		
	B40	WO-93/20235	10-14-1993	Univ Johns Hopkins Med		
	B41	WO-94/00603	01-06-1994	Univ Princeton et al.		
	B42	WO-94/01447	01-20-1994	Eriphyle B V et al.		
	B43	WO-94/10575	05-11-1994	Rycus Avigail et al.		
	B44	WO-94/11383	05-26-1994	Cold Spring Harbor Lab		
	B45	WO-95/00669 A	01-05-1995	Pharmacia Biotech Ab et al.		√
	B46	WO-95/07361	03-16-1995	Pasteur Institut et al.		
	B47	WO-95/09928	04-13-1995	Univ California		
	B48	WO-95/09929	04-13-1995	Univ California		
	B49	WO-95/13397	05-18-1995	Univ Johns Hopkins Med		
	B50	WO-95/15400	06-08-1995	Univ Johns Hopkins		
	B51	WO-95/16792	06-22-1995	Stroun Maurice et al.		√
	B52	WO-95/18818	07-13-1995	Philadelphia Children Hospital		
	B53	WO-95/19448	07-20-1995	Univ Johns Hopkins Med		
	B54	WO-95/25813	09-28-1995	Univ Utah Res Found et al.		
	B55	WO-96/01907	01-25-1996	Squibb Bristol Myers Co		
	B56	WO-96/06951	03-07-1996	Univ Johns Hopkins Med et al.		
	B57	WO-96/08514	03-21-1996	Tsang Kwong Y et al.		
	B58	WO-97/07239	02-27-1997	Max Planck Gesellschaft et al.		√
	B59	WO-97/09600	03-13-1997	Medical Res Council et al.		
	B60	WO-97/19191 A	05-29-1997	Oegreid Dagfinn et al.		
	B61	WO-97/23651	07-03-1997	Exact Lab Inc		

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SA/



Substitute for form 1449/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	10/601,132
		Filing Date	June 20, 2003
		First Named Inventor	Anthony P. Shuber
		Art Unit	1642
		Examiner Name	S. E. Aeder
Sheet	6	of	11
		Attorney Docket Number	EXT-055

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	†
	B62	WO-97/28450	08-07-1997	Exact Lab Inc		
	B63	WO-98/08971	03-05-1998	Invitex GmbH et al.		✓
	B64	WO-98/38338	09-03-1998	Exact Lab Inc		
	B65	WO-98/39478	09-11-1998	Exact Lab Inc		
	B66	WO-98/58081	12-23-1998	Exact Lab Inc		
	B67	WO-98/58084	12-23-1998	Exact Lab Inc		
	B68	WO-99/07894	02-18-1999	Wisconsin Alumni Res Found et al.		
	B69	WO-99/07895	02-18-1999	Ludwig Inst Cancer Res et al.		
	B70	WO-99/10528	03-04-1999	Giesing Michael et al.		✓
	B71	WO-99/20798	04-29-1999	Exact Lab Inc		
	B72	WO-99/26724	06-03-1999	Mosaic Technologies et al.		
	B73	WO-99/28507	06-10-1999	Exact Lab Inc		
	B74	WO-99/53316	10-21-1999	Exact Lab Inc		
	B75	WO-99/55912	11-04-1999	Exact Lab Inc		
	B76	WO-99/66077	12-23-1999	Exact Lab Inc		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.  
 †Applicant's unique citation designation number (optional).  
 ‡Applicant is to place a check mark here if English language Translation is attached.

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(ii)) because that application was filed after June 30, 2003 or is available in the IPW. † Applicant's unique citation designation number (optional). ‡ See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. ‡ Error Office that issued the document, by the two-letter code (WFO Standard ST.3). ‡ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ‡ Kind of document by the appropriate symbols as indicated on the document under WFO Standard ST.16 if possible. ‡ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				†
	C1	Alquist et al. "Universal Detection of Aerodigestive Cancers by Assay of Nanopoptotic Human DNA in Stool." Presented at Digestive Diseases Week Annual Conference, San Diego, CA, May 2000.				
	C2	Aaltonen et al. (1994) "Replication Errors in Benign and Malignant Tumors from Hereditary Nonpolyposis Colorectal Cancer Patients" Cancer Research 54: 1645-1648.				
	C3	Aaltonen et al. (1998) "Incidence of Hereditary Nonpolyposis Colorectal Cancer and the Feasibility of Molecular Screening for the Disease" The New England Journal of Medicine 338: 1481-1487.				

Examiner Signature	Date Considered
--------------------	-----------------

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SA/

Substitute for form 1449/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			Application Number	10/601,132	
			Filing Date	June 20, 2003	
			First Named Inventor	Anthony P. Shuber	
			Art Unit	1642	
			Examiner Name	S. E. Aeder	
Sheet	7	of	11	Attorney Docket Number	EXT-055

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
	C4	Allen et al. (1997) "Morphological and biochemical characterization and analysis of apoptotis." J Pharm. & Toxicol. Methods, Vol. 37, No. 4, pp. 215-28.		
	C5	Ambrosini et al. "A novel anti-apoptosis gene, surviving, expressed in cancer and lymphoma" Nature Medicine, Vol. 3, No. 8, pp. 917-921, August 1997.		
	C6	Anker et al. (1999) "Detection of Circulating Tumour DNA in the Blood (plasma/serum) of Cancer Patients," Cancer and Metastasis Reviews, Vol. 18, pp.65-73.		
	C7	Arber et al. (1997) "A K-ras Oncogene Increases Resistance to Sulindac-Induced Apoptosis in Rat Enterocytes," Gastroenterology, Vol. 113, No. 6, pp. 1892-1900.		
	C8	Bernstein et al. "A Bile Acid-induced Apoptosis Assay for Colon-Cancer Risk and Associated Quality Control Studies," Cancer Research, Vol. 59, pp. 2353-2357, 1999.		
	C9	Bertario et al. (1999) "Risk of Colorectal Cancer Following Colonoscopic Polypectomy," Tumori 85: 157-162.		
	C10	Blum (1995) "Colorectal Cancer: Future Population Screening for Early Colorectal Cancer," European Journal of Cancer, Vol. 31A, pp. 1369-1372.		
	C11	Bohm et al. (1977) "Deletion Analysis at the DEL-27, APC and MTS1 Loci in Bladder Cancer: LOH at the DEL-27 Locus on 5p13-12 is a Prognostic Marker of Tumor Progression," Int. J. Cancer (Pred. Oncol.), 74:291-295.		
	C12	Bos et al. (May 28, 1987) "Prevalence of ras Gene Mutations in Human Colorectal Cancers," Nature, Vol. 327, pp. 293-297.		
	C13	Caldas et al. (1994) "Detection of K-ras Mutations in the Stool of Patients with Pancreatic Adenocarcinoma and Pancreatic Ductal Hyperplasia," Cancer Research, Vol. 54, pp. 3568-3573.		
	C14	Capozzi et al. (1999) "Evaluation of the Replication Error Phenotype in Relation to Molecular and Clinicopathological Features in Hereditary and Early Onset Colorectal Cancer," European Journal of Cancer 35: 289-295.		
	C15	Cave et al. (1994) "Reliability of PCR Directly from Stool Samples: Usefulness of an Internal Standard," BioTechniques, Vol. 16, No. 5, pp. 809-810.		
	C16	Cawkwell et al. (1994) "Frequency of allele loss of DCC, p53, Rb1, Wt1, NF1, NM23 and APC/MCC in colorectal cancer assayed by fluorescent multiplex polymerase chain reaction," B. J. Can., Vol. 70, pp. 813-818.		
	C17	Chapelle (1999) "Testing Tumors for Microsatellite Instability," European Journal of Human Genetics 7: 407-408.		
	C18	Charlesworth et al. (1994) "The Evolutionary Dynamics of Repetitive DNA in Eukaryotes," Nature, Vol. 371, pp. 215-220.		
	C19	Chen et al. (1997) "Microsatellite Instability in Sporadic-Colon-Cancer Patients With and Without Liver Metastases" International Journal of Cancer 74: 470-474.		
	C20	Chen et al. (1996), "Detection of Single-Base Mutations by a Competitive Mobility Shift Assay," Analytical Biochemistry, C.I.S. Academic Press, Vol. 239, No. 1, pp. 61-69.		
	C21	Coll et al. (1989) "Evaluation of a Rapid Method of Extracting DNA from Stool Samples for Use in Hybridization Assays," Journal of Clinical Microbiology, Vol. 27, No. 10, pp. 2245-2248.		
	C22	Coombs et al. (1996) "A Rapid, Simple, and User-Friendly Method for DNA Extraction from Clinical Stool Samples," ASM 1996 General Meeting, New Orleans, LA.		

Examiner Signature	Date Considered
--------------------	-----------------

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SA/

Substitute for form 1449/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			Application Number	10/601,132	
			Filing Date	June 20, 2003	
			First Named Inventor	Anthony P. Shuber	
			Art Unit	1642	
			Examiner Name	S. E. Aeder	
Sheet	8	of	11	Attorney Docket Number	EXT-055

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No.	include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	C23	Coughlin et al. (1999) "Public Health Perspectives on Testing for Colorectal Cancer Susceptibility Genes" American Journal of Preventive Medicine 16: 99-104.		
	C24	Croitoru et al. "Reduce, Reuse, and Recycle: Shedding Light on Shedding Cells," Gastroenterology, Vol. 105, pp. 1243-1246, October 1993.		
	C25	Cunningham C. and M.G. Dunlop, (1996) "Molecular Genetic Basis of Colorectal Cancer Susceptibility," British Journal of Surgery, Vol. 83, pp. 321-329.		
	C26	Deng et al. (1996) "Loss of Heterozygosity in Normal Tissue Adjacent to Breast Carcinomas," Science, Vol. 274, pp. 2057-2059.		
	C27	Dennin (1979) "DNA of Free and Complexed Origin in Human Plasma: Concentration and Length Distribution," Klin. Wochenschr. Vol. 57, pp. 451-456.		
	C28	Depraetere "Eat me- Signals of apoptotic bodies," Nature Cell Biology, Vol. 2, pg. E 104, June 2000.		
	C29	Deuter et al. (1995) "A Method for Preparation of Fecal DNA Suitable for PCR," Nucleic Acids Research, Vol. 23, No. 18, pp. 3800-3801.		
	C30	Dib et al. (1996) "A Comprehensive Genetic Map of the Human Genome Based on 5,264 Microsatellites," Nature Vol. 380, pp. 152-154.		
	C31	Duffy (1995) "Can Molecular Markers Now be Used for Early Diagnosis of Malignancy?" Clin. Chem, Vol. 41, No. 10, pp. 1410-1413.		
	C32	Eads et al. (1999) "CpG island hypermethylation in human colorectal tumors is not associated with DNA methyltransferase overexpression." Cancer Research, Vol. 59, No. 10, pp. 2301-2306.		
	C33	Eguchi et al. (1996) "Mutations of the p53 Gene in the Stool of Patients with Resectable Colorectal Cancer," Cancer Supplement, Vol. 77, No. 8, pp. 1707-1710.		
	C34	Emien et al. (1984) "Effect of DNA Size and Strandedness on the <i>in vivo</i> Clearance and Organ Localization of DNA," Clin. Exp. Immunol., Vol. 56, pp. 185-192.		
	C35	Fearon (1995) "Molecular Abnormalities in Colon and Rectal Cancer," The Molecular Basis of Cancer, pp. 340-357.		
	C36	Finkel (1999) "Does Cancer Therapy Trigger Cell Suicide?," Science, Vol. 286, pp. 2256-2258.		
	C37	Garewal et al. (1996) "Reduced Bile Acid-induced Apoptosis in "Normal," Colorectal Mucosa: A Potential Biological Marker for Cancer Risk" Cancer Research, Vol. 56, pp. 1480-1483.		
	C38	Giacona et al. (1998) "Cell-Free DNA in Human Blood Plasma: Length Measurements in Patients with Pancreatic Cancer and Healthy Controls," Pancreas, Vol. 17, No. 1, pp. 89-97.		
	C39	Grossman et al. (1988), "Colonoscopic Screening of persons With Suspected Risk Factors for Colon Cancer," Gastroenterology 94: 395-400.		
	C40	Gyllenstein et al. (1995) "Sequencing of In Vitro Amplified DNA," Recombinant DNA Methodology II, (Wu, ed.), pp. 565-578.		
	C41	Hall et al. "Regulation of cell number in the mammalian gastrointestinal tract: the importance of apoptosis," Journal of Cell Science, Vol. 107, pp. 3569-3577, 1994.		
	C42	Hasegawa et al. (1995) "Detection of K-ras Mutations in DNAs Isolated From Feces of Patients with Colorectal Tumors by Mutant-Allele-Specific Amplification (MASA)," Oncogene, Vol. 10, pp. 1441-1445.		

Examiner Signature	Date Considered
--------------------	-----------------

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SA/

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>			<b>Complete if Known</b>		
			Application Number	10/601,132	
			Filing Date	June 20, 2003	
			First Named Inventor	Anthony P. Shuber	
			Art Unit	1642	
Examiner Name	S. E. Aeder				
Attorney Docket Number	EXT-055				
Sheet	9	of	11		

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	C43	Hettis "To Die or Not to Die, An Overview of Apoptosis and Its Role in Disease," JAMA, Vol. 279, No. 4, pp. 300-307, January 28, 1998.		
	C44	Hibi et al. (1998) "Molecular Detection of Genetic Alterations in the Serum of Colorectal Cancer Patients," Cancer Research, Vol. 58, pp. 1405-1407.		
	C45	Hickman et al. (1994), "Apoptosis and cancer chemotherapy," Phil. Trans. R. Soc. Lond., 345:319-325.		
	C46	Hoang et al. (1997) "BAT-26, an Indicator of the Replication Error Phenotype in Colorectal Cancers and Cell Lines" Cancer Research 57: 300-303.		
	C47	Honchel et al. (1995) "Genomic Instability in Neoplasia," Seminars in Cell Biology, Vol. 6, pp. 45-52.		
	C48	Iino et al. (1999) "DNA Microsatellite Instability in Hyperplastic Polyps, Serrated Adenomas, and Mixed Polyps: a Mild Mutator Pathway for Colorectal Cancer?" Journal of Clinical Pathology 52: 5-9.		
	C49	Iriesta et al. (1998) "Genetic Abnormalities and Microsatellite Instability in Colorectal Cancer," Cancer Detection and Prevention 22: 383-395.		
	C50	Ishimaru et al. (1995) "Microsatellite Instability in Primary and Metastatic Colorectal Cancers," International Journal of Cancer 64: 153-157.		
	C51	Jarvinen et al. (1995) "Screening Reduces Colorectal Cancer Rate in Families With Hereditary Nonpolyposis Colorectal Cancer," Gastroenterology 108: 1405-1411.		
	C52	Jernvall et al. (1999) "Microsatellite Instability: Impact on Cancer Progression in Proximal and Distal Colorectal Cancers," European Journal of Cancer 35: 197-201.		
	C53	Jessup et al. (1992) "The Biology of Colorectal Carcinoma," Current Problems in Cancer pp. 263-328.		
	C54	Kawakami et al. (2000) "Hypermethylated APC DNA in Plasma and Prognosis of Patients with Colorectal Carcinoma," Int. J. Cancer (Pred. Oncol.) 84:404-409.		
	C55	Kawasaki et al. (1998) "Inhibition of Apoptosis by Surviving Predicts Shorter Survival Rates in Colorectal Cancer," Cancer Research, Vol. 58, pp. 5071-5074.		
	C56	Kim et al. (1998) "Microsatellite Instability in Young Patients With Colorectal Cancer," Pathology International 48: 586-594.		
	C57	Ko et al. (1999) "Genomic Instability and Alterations in Apc, Mcc and Dcc in Hong Kong Patients with Colorectal Carcinoma," Int. J. Cancer (Pred. Oncol.), 84:404-409.		
	C58	Konishi et al. (1996) "Molecular Nature of Colon Tumors in Hereditary Nonpolyposis Colon Cancer, Familial Polyposis, and Sporadic Colon Cancer," Gastroenterology 111: 307-317.		
	C59	Lamberti et al. (1999) "Microsatellite Instability - a Useful Diagnostic Tool to Select Patients at High Risk for Hereditary Non-Polyposis Colorectal Cancer: A Study in Different Groups of Patients With Colorectal Cancer," Gut 44: 839-843.		
	C60	Lengauer et al. (1998) "Genetic Instabilities in Human Cancers," Nature, Vol. 396, pp. 643-649.		
	C61	Leon et al. (1977) "Free DNA in the Serum of Cancer Patients and the Effect of Therapy," Cancer Research, Vol. 37, pp. 646-650.		

Examiner Signature	Date Considered
--------------------	-----------------

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SA/

Substitute for form 1449/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			Application Number	10/601,132	
			Filing Date	June 20, 2003	
			First Named Inventor	Anthony P. Shuber	
			Art Unit	1642	
			Examiner Name	S. E. Aeder	
Sheet	10	of	11	Attorney Docket Number	EXT-055

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T*	
	C62	Lipkin "Biomarkers of Increased Susceptibility to Gastrointestinal Cancer: New Application to Studies of Cancer Prevention in Human Subjects," Cancer Research, Vol. 48, pp. 235-245, January 15, 1998.		
	C63	Lleonart et al. (1998) "Microsatellite Instability and p53 Mutations in Sporadic Right and Left Colon Carcinoma" American Cancer Society 83: 889-895.		
	C64	Loktionov et al. (1995) "Early Detection of Cancer-Associated Gene Alterations in DNA Isolated from Rat Feces During Intestinal Tumor Induction with 1,2-Dimethylhydrazine," International Journal of Oncology, Vol. 6, pp. 437-445.		
	C65	Mulcahy et al. (February 1998) "A Prospective Study of K-ras Mutations in the Plasma of Pancreatic Cancer Patients," Clinical Cancer Research Vol. 4, pp. 271-275.		
	C66	Nollau et al. (1996) "Detection of K-ras Mutations in Stools of Patients with Colorectal Cancer by Mutant-Enriched PCR," Int. J. Cancer, Vol. 66 pp. 332-336.		
	C67	Nollau et al. (May 1996) "Isolation of DNA from Stool and Bodily Fluids for PCR Amplification," BioTechniques, Vol. 20, No. 5, pp. 784-788.		
	C68	Park et al. (1999) "Gene-Environment Interaction in Hereditary Nonpolyposis Colorectal Cancer with Implications for Diagnosis and Genetic Testing," International Journal of Cancer 82: 516-519.		
	C69	Payne et al. "Role of Apoptosis in Biology and Pathology: Resistance to Apoptosis in Colon Carcinomas & Ultrastructural Pathology," Vol. 19, pp. 221-248, 1995.		
	C70	Ponz de Leon et al. (1998) "Frequency and Type of Colorectal Tumors in Asymptomatic High-Risk Individuals in Families with Hereditary Nonpolyposis Colorectal Cancer," Cancer Epidemiology, Biomarkers & Prevention 7: 639-641.		
	C71	Ponz de Leon et al. (1999) "Hereditary Colorectal Cancer in the General Population: From Cancer Registration to Molecular Diagnosis," Gut 45: 32-38.		
	C72	Pyatt et al. (1999) "Polymorphic Variation at the BAT-25 and BAT-26 Loci in Individuals of African Origin," American Journal of Pathology 155: 349-353.		
	C73	Rashid et al. (1999) "Genetic Epidemiology of Mutated K-ras Proto-Oncogene, Altered Suppressor Genes, and Microsatellite Instability in Colorectal Adenomas," Gut 44: 826-833.		
	C74	Ravellingien et al. (1995) "Contribution of Molecular Oncology in the Detection of Colorectal Carcinomas," Acta Gastro-Enterologica Belgica, Vol. 58, pp. 270-273.		
	C75	Ridanpaa et al. (1995) "Detection of Loss of Heterozygosity in the p53 Tumor Suppressor Gene Using a PCR-based Assay," Path. Res. Pract., Vol. 191, pp. 399-402.		
	C76	Salahshor et al. (1999) "Microsatellite Instability in Sporadic Colorectal Cancer is Not an Independent Prognostic Factor" British Journal of Cancer 81: 190-193.		
	C77	Samowitz et al. (1995) "Microsatellite Instability in Human Colonic Cancer is Not a Useful Clinical Indicator of Familial Colorectal Cancer," Gastroenterology 109: 1765-1771.		
	C78	Samowitz et al. (1997) "Microsatellite Instability in Colorectal Adenomas," Gastroenterology 112: 1515-1519.		
	C79	Samowitz et al. (1999) "BAT-26 and BAT-40 Instability in Colorectal Adenomas and Carcinomas and Germline Polymorphisms," American Journal of Pathology 154: 1637-1641.		

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SA/

Substitute for form 1449/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				Application Number	10/601,132
				Filing Date	June 20, 2003
				First Named Inventor	Anthony P. Shuber
				Art Unit	1642
				Examiner Name	S. E. Aeder
Sheet	11	of	11	Attorney Docket Number	EXT-055

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
	C80	Shapiro et al. (June 1983) "Determination of Circulating DNA Levels in Patients with Benign or Malignant Gastrointestinal Disease," Cancer, Vol. 51, No. 11, pp. 2116-2120.			
	C81	Sidransky (1997) "Nucleic acid-based methods for the detection of cancer," Science, Vol. 278, No. 5340, pp. 1054-1057.			
	C82	Sidransky et al. (1992) "Identification of ras Oncogene Mutations in the Stool of Patients with Curable Colorectal Tumors," Science, Vol. 256, pp. 102-105.			
	C83	Skoletsky et al. (1998) "High frequency of detecting amplifiable DNA in stools of apparently normal individuals," Gastroenterology, Vol. 114, No. 4, p A681.			
	C84	Smith-Ravin et al. (1995) "Detection of c-Ki-ras Mutations in Fecal Samples from Sporadic Colorectal Cancer Patients," Gut, Vol. 36, pp. 81-86.			
	C85	Syngal et al. (1998) "Benefits of Colonoscopic Surveillance and Prophylactic Colectomy in Patients With Hereditary Nonpolyposis Colorectal Cancer Mutations," Annals of Internal Medicine 129: 787-796.			
	C86	Syngal et al. (1999) "Interpretation of Genetic Test Results for Hereditary Nonpolyposis Colorectal Cancer," JAMA 282: 247.			
	C87	Takeda et al. (1993) "Detection of K-ras Mutation in Sputum by Mutant-Allele-Specific Amplification (MASA)," Human Mutation, Vol. 2, pp. 112-117.			
	C88	Thibodeau et al. (1993) "Microsatellite Instability in Cancer of the Proximal Colon," Science, Vol. 260, pp. 816-819.			
	C89	Tsujitani et al. (1996) "Apoptotic Cell Death and Its Relationship to Carcinogenesis in Colorectal Carcinoma," Cancer Supplement, Vol. 77, No. 8, pp. 1711-1716.			
	C90	Vogelstein, et al. (1999) "Digital PCR," Proc. Natl. Acad. Sci. USA, Vol. 96, pp. 3543-3557.			
	C91	Zhou et al. (1997) "Allelic Profiles of Mononucleotide Repeat Microsatellites in Control Individuals and in Colorectal Tumors With and Without Replication Errors," Oncogene 15: 1713-1718.			
	C92	Zhou et al. (1998) "Determination of the Replication Error Phenotype in Human Tumors Without the Requirement for Matching Normal DNA by Analysis of Mononucleotide Repeat Microsatellites," Genes. Chromosomes & Cancer 21: 101-107.			

LIBC:3251029.1

Examiner Signature	/Sean Aeder/ (10/17/2008)	Date Considered	
--------------------	---------------------------	-----------------	--

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /SA/